REMARKS/ARGUMENTS

The rejections presented in the Office Action dated March 25, 2008 (hereinafter Office Action) have been considered. Claims 1-23 and 25-66 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 2, 4-7, 9, 13, 15, 18, 19, 21, 22, 27, 28, 30, 48, 49, and 52 are rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,282,444 to *Kroll et al.* (hereinafter "*Kroll*"). Claims 1, 2, 4-7, 11, 16-19, 21, 22, 25, 31, 32, 48, 49, 53, and 54 are rejected based on 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,190,997 to *Darvish et al.* (hereinafter "*Darvish*"). Claims 55, 58, and 64 are rejected based on 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over *Kroll*. Claims 55, 56, 65, and 66 are rejected based on 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over *Darvish*. Claims 3, 8, 10, 12, 14, 20, 23, 26, 29, 50, 51, 53, 57, and 63 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Kroll* or *Darvish*. Claims 59-62 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Kroll* or *Darvish*.

The Applicant herein references the remarks presented in the Office Action Response filed 12/28/2007. The Applicant reiterates these remarks in response to the rejections and refrains from fully reprinting them herein for brevity. The Applicant addresses the Examiner's "Response to Arguments" below.

The Applicant has previously contended that both *Kroll* and *Darvish* fail to teach a cardiac electrode supported by the lead body, the electrode configured for subcutaneous, non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation, in the manner claimed in each of claims 1, 18, 48, and 55.

In addressing these contentions, the Office Action states that:

> Kroll includes inherent disclosure of these features. For instance, even if Kroll did not provide the explicit disclosure of "transthoracic pacing,"

Kroll's intracardiac electrodes are capable of subcutaneous placement because they are of a size and material capable of placement between the skin and ribs. (Page 8; see page 9 regarding Darvish).

The Applicant respectfully submits that the statements regarding what the *Kroll* and *Darvish* devices are capable of are unsupported and comprised of speculation. There is no evidence on the record to support this speculation. Moreover, the *Kroll* and *Darvish* references themselves undermine such a contention by specifically locating the respective leads and electrodes on and within the heart to carryout the disclosed functions. (See Figs. 2-4 of *Kroll* and Fig. 1 of *Darvish*). The Applicant respectfully requests the requisite evidence that *Kroll*'s and *Darvish's* leads are actually capable of what is proposed in the Office Action.

Additionally, the Applicant notes that the above contention of the Office Action relies on what is inherently disclosed in *Kroll* and *Darvish*.

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (MPEP § 2112(IV) quoting *In re Rijckaert*, 9 F.3d 1531, 1534, (Fed. Cir. 1993)).

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." (MPEP §2131.01(III) quoting *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)). The Applicant respectfully submits that the Office Action fails to provide the requisite extrinsic evidence regarding the capabilities of the leads and electrodes of *Kroll* and *Darvish*. Absent such evidence, the anticipation rejection of independent claims 1, 18, 48, and 55 is incomplete and in error.

The Applicant's independent claims 1, 48, and 55 each recite, among other features, some variation of a pharmacological agent provided along at least a longitudinal portion of

an exterior surface of the lead body. The Applicant's independent claims 18 and 55 recite some variation of a pharmacological agent provided on a portion of an exterior surface of the can.

In addressing these limitations, the Office Action notes that *Kroll* discloses a biocide that may be provided "surrounding the cardiac stimulation device." (Pages 2 and 9 of Office Action; *see Kroll*, Col. 11, Lines 65-67). *Kroll* does not appear to elaborate in which manner the biocide surrounds the cardiac stimulation device. As such, it cannot be concluded that *Kroll* necessarily teaches such particulars as the biocide along at least a longitudinal portion of an exterior surface of the lead body, in the manner claimed in independent claims 1, 48, and 55. Moreover, a biocide surrounding a device does not include the particulars of actually being <u>on</u> a portion of an exterior surface of the can, as claimed in independent claims 18 and 55.

For example, a person's aorta is surrounded by the person's skin, but one having ordinary skill in the relevant art would not reasonably conclude that the patient's skin is provided along at least a longitudinal portion of an exterior surface of the aorta or on the aorta surface. Similarly, just because *Kroll's* device is surrounded by biocide does not mean that the biocide satisfies the particulars of being provided along at least a longitudinal portion of an exterior surface of a lead body or on a can surface.

The Office Action further states that:

> Even if the lead is not considered part of the device, the biocide is "along at least a longitudinal portion of an exterior surface of the lead body" over the portion of the lead that passes through the biocide that surrounds the can. (Page 9).

The Applicant respectfully submits that *Kroll* states that the biocide surrounds the device (not just the can). (Col. 11, Lines 65-67). As such, it does not appear that there is support in *Kroll* for the hypothetical "portion of the lead that passes through the biocide that surrounds the can." (quoting Page 9 of the Office Action).

For these reasons, the Applicant's respectfully submits that the Office Action's reliance on *Kroll's* disclosure of a biocide surrounding a device as anticipating the particular claimed elements is misplaced.

Regarding these claim elements and *Darvish*, *Darvish* discloses that a "molecular source is integral with said at least one electrode" (Col. 5, Line 8) and later that "one electrode comprises a linear electrode" (Col. 6, Line 30). The Applicant respectfully submits that it is not necessarily the case that the molecular source is then provided along at least a longitudinal portion of an exterior surface of the lead body. The molecular source could be disposed on a single point on, or even a ring around, the electrode. As such, the area of deposition is not necessarily along a longitudinal portion of the linear electrode, and to find otherwise would require reliance upon teachings that are not actually provided by *Darvish*.

In addressing the Applicant's contentions in this regard, the Office Action states that "even if the agent is provided from a point or a ring, the point or ring traverses some longitudinal portion because it cannot have zero width."

Claims must be given their broadest reasonable interpretation consistent with the specification, as it would be interpreted by one of ordinary skill in the art. (*Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)(citing *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004)); see MPEP § 2111). The Applicant respectfully submits that an interpretation of the claimed pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body as anything that does not have zero width is unreasonable. One having ordinary skill in the art would not reasonably regard something with a close-to-zero width as being provided over a longitudinal portion. Claim terms must be given meaning, and it appears that the Office Action is interpreting "longitudinal" in a manner that strips the claim term of meaning.

The Office Action also points out on Page 10 that *Darvish* states that "the catheter may be drug-eluting over a portion of its length" (Col. 16, Line 23). This portion of *Darvish* is describing Fig. 5, which shows an electrode 192 separate from the catheter 188. One having ordinary skill in the art will understand that this eluting catheter 188 is a not a

lead, especially considering that *Darvish's* preceding Fig. 4 does show and describe a lead 180 (Col. 15, Lines 30-55), which is not disclosed to have the property of drug-eluting over a portion of its length.

For each of the reasons discussed above, the Applicant respectfully submits that the rejections of independent claims 1, 18, 48, and 55 based on *Kroll* and *Darvish* are improper and must be withdrawn.

The Applicant's independent claims 1, 48, and 55 each further recite, among other features, some variation of a driving arrangement coupled to the lead, the driving arrangement configured to provide phoresis delivery of a pharmacological agent from the longitudinal portion of the exterior surface of the lead body to subcutaneous tissue. The Applicant's independent claims 18 and 55 each recite some variation of a pharmacological agent provided on a portion of an exterior surface of the can, wherein the can is configured to provide phoresis delivery of the pharmacological agent from at least the portion of the exterior surface of the can to subcutaneous tissue.

The Office Action appears to contend that *Kroll's* device is configured to provide phoresis delivery merely for the reason that biocide is provided around the device and that the device delivers pacing and sterilization shocks. (Page 9). The Applicant respectfully submits that this interpretation is based on speculation and is unsupported by *Kroll*.

For example, no disclosure is made that *Kroll's* biocide would be influenced by an electrical gradient.

Moreover, considering that *Kroll's* shocks would be delivered between electrodes, it would seem that the biocide would need to be between the electrodes. However, *Kroll* does not disclose that the biocide would be between electrodes.

The Office Action also states that *Kroll* arguably provides phoresis delivery from a coating on the can because phoresis merely means "delivery." (Page 9). However, as discussed above, *Kroll* does not provide a *coating* of biocide.

Additionally, it would appear that the Office Action is interpreting use of the claim term phoresis in such a way that the word has no meaning. The Applicant has specific

limitations regarding a driving arrangement configured to provide phoresis delivery of a pharmacological agent from the longitudinal portion of the exterior surface of the lead body, for example. It is unclear how *Kroll's* provision of biocide around a device would constitute a driving arrangement configured to provide phoresis delivery of a pharmacological agent from the longitudinal portion of the exterior surface of the lead body.

For these reasons, the Applicant's respectfully submits that the Office Action's reliance on *Kroll's* disclosure of a biocide surrounding a device as anticipating the particular claimed elements is misplaced.

For the reasons discussed above and presented in the previous response, the Applicant respectfully submits that the rejections based on *Kroll* and *Darvish* of independent claims 1, 18, 48, and 55, and dependent claims 2-17, 19-23 and 25-47, 49-54, and 56-66 which respectively depend therefrom, are improper and must be withdrawn.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, what things are capable of, what is inherent, what is well known in the art, common knowledge at the time of the Applicant's invention, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.626PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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